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**Filed** : February 6, 2002

### REMARKS

Claims 26-30, 32, and 45 are pending in the instant application. By way of this amendment, Claim 27 has been cancelled and Claim 28 amended to correct the antecedent basis of the subject matter of Claim 28. Specifically, the subject matter of Claim 27 has been moved into Claim 26 and Claim 28 has been amended to depend from Claim 26. New Claims 46-48, directed to colorants and fragrances that can be included in the claimed compositions, have been added. Support for this amendment can be found throughout the specification and claims as originally filed, for example, at paragraphs [0042] and [0050] and original Claims 10-12. Accordingly, no new matter has been added to the application.

Applicants thank the Examiner for withdrawal of the claim rejections under 35 U.S.C. § 102(b).

In view of the remarks set forth below, Applicant respectfully requests reconsideration of the application and submits that the application is in condition for allowance.

#### Rejection Under 35 U.S.C. § 103

The Examiner has maintained the rejection of Claims 26-30, 32, and 45 under 35 U.S.C. § 103(a) as being unpatentable over Hellstrand et al., WO 97/42968 (WO '968) in view of Bruce et al., WO 95/23601 (WO '601), further in view of Bathurst *et al.*, U.S. Patent No. 6,004,579 (the '579 patent).

The Examiner notes that neither WO '968 nor WO '601 discloses a method for making a composition wherein histamine phosphate is the active ingredient and is also formulated to contain fragrance and colorants. The Examiner asserts that the '579 patent discloses a method of making a topical composition for the treatment of dermatological compositions; said compositions formulated as liquids, creams, lotion, ointment, suntan lotion, sunscreen, etc. The Examiner asserts that one of ordinary skill in the art would expect to obtain a cosmetic composition such as creams, gels, lotions and sunscreens that upon topical application to the skin allow the skin to heal and resist cell damage as well as restore normal skin function. The Examiner states that the motivation to combine the references lies in the reasonable expectation of success in achieving the beneficial effects of the composition in treating various dermatological conditions as disclosed in the '579 patent.

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To establish a *prima facie* case of obviousness, three basic criteria must be met: first, there must be a suggestion or motivation to modify the reference to achieve the claimed invention; second, there must be a reasonable expectation of success derived from the cited reference in practicing the claimed invention; and third, the cited references must teach or suggest all the limitations of the claimed invention. M.P.E.P. § 2143. “The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure.” *Id.* (citing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)). (Emphasis added.) Without a motivation to combine, a rejection based on a *prima facie* case of obviousness is improper. See M.P.E.P. § 2143.01.

Applicant respectfully submits that there is no teaching or suggestion provided in the cited references to make the claimed combination of references. Accordingly, the Examiner has failed to establish a *prima facie* case of obviousness and that the present rejection should be withdrawn.

The pending claims of the instant application relate to a method for making a cosmetic composition, wherein the composition comprises an effective dose of a compound that inhibits the production and release of ROMs in an amount effective to treat disorders of the skin, and a cosmetically acceptable carrier.

The Examiner asserts that WO ‘968 discloses a composition for topical application and treatment of skin diseases and conditions including sunburn, thermal burn and other lesions. However, a review of this reference reveals that WO ‘968 discloses the systemic administration of histamine to establish stable levels of histamine in the blood.

Contrary to the Examiner’s assertion, the reference does not disclose the topical application of histamine to treat disorders of the skin or mucosa, much less teach or suggest the cosmetic compositions claimed in the instant application. Moreover, a person of skill in the art would not be motivated to topically apply the histamine compounds to achieve the desired result taught in WO ‘968, i.e., to establish stable levels of histamine in the blood. Accordingly, this reference teaches away from the topical application of histamine and related compounds and therefore cannot be relied upon as a primary reference. A person of ordinary skill in the art, reading this reference, would be motivated to employ a systemic route of delivery to establish stable levels of histamine in the blood, and thus, would not be motivated to combine the cited

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references to achieve the claimed cosmetic compositions. A reference that teaches away from the invention cannot be used in a *prima facie* case of obviousness, because it is improper to combine references where the references teach away from the combination. M.P.E.P. § 2145(X)(D)(2) (citing *In re Grasselli*, 713 F.2d 731, 743, 218 U.S.P.Q. 769, 779 (Fed. Cir. 1983)). Accordingly, Applicants respectfully submit that the PTO has failed to establish a *prima facie* case of obviousness due to its reliance upon WO '968 as a primary reference. Thus, the claims are not obvious in view of the asserted combination of references. Nevertheless, the deficiencies of the combination of the remaining two references are discussed below.

WO '601 describes a method and composition for topical treatment of damaged skin tissue. The composition specifically comprises histamine phosphate as the active ingredient. The composition disclosed in WO '601 is described throughout the disclosure as providing "an effective remedy," or "an improved medication and treatment," or the like. The reference discloses that the histamine phosphate compositions are "very effective" in preventing and or minimizing lesions resulting from the recited skin conditions, or minimizing the duration and pain from such lesions. See WO '601 at page 11, lines 16-19. The reference does not teach or suggest a cosmetic composition which, in addition to treating the underlying condition, improves the immediate appearance of the patient.

As discussed previously, unlike traditional therapeutic agents that simply treat a disease, cosmetic compositions focus on the treatment of the disease while simultaneously addressing the patient's aesthetic concerns. Accordingly, cosmetic compositions include ingredients such as color, fragrance, and texture, or any other aesthetic features. This difference between a traditional therapeutic composition and a cosmetic composition is substantial from a patient's perspective when considering the aesthetics of disease treatment.

Prior to the claimed invention, methods for making cosmetic compositions comprising histamine and histamine related compounds in a cosmetically acceptable carrier were not contemplated. The benefits of formulating such compositions to take into account a patient's aesthetic concerns were unrecognized. WO '601 does not consider, much less address, a patient's aesthetic concerns, and thus, cannot provide a teaching or suggestion to alter the disclosed methods and compositions to achieve a benefit that was not recognized. Accordingly, WO '601 does not teach or suggest a method for making cosmetic compositions for topically delivering a compound that inhibits the production and release of enzymatically produced ROMs.

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Nevertheless, the Examiner asserts that the claimed invention is obvious in view of the '579 patent, which teaches that the phospholipid-containing compositions disclosed therein can be formulated into various topically acceptable liquids, creams, lotions, gels, etc. The Examiner asserts that the motivation to combine the references lies in the reasonable expectation of success in achieving the beneficial effects of the composition in treating various dermatological conditions as disclosed in the '579 patent.

The '579 patent discloses compositions comprising phospholipids as active components for the topical treatment of dermatologic conditions in which apoptosis is implicated, such as conditions and diseases related to aging. The '579 patent discloses that such conditions include wrinkling or sagging due to age and/or photo damage or psoriasis or hair loss. See, the '579 patent at col. 14, lines 41-51. The '579 patent discloses that the phospholipid compositions can be topically administered via a cosmetically acceptable carrier. However, there is no teaching or suggestion in the '579 patent to use cosmetic carriers with compositions other than phospholipid compositions disclosed therein, namely Elirex™. Thus, the necessary suggestion or motivation to combine WO '601 and the '579 patent is absent.

Moreover, the cited combination does not provide one of skill in the art with a reasonable expectation of success in practicing the claimed invention. As discussed above, WO '601 does not disclose the benefits of administering compounds in cosmetically acceptable carriers. In addition, there is no discussion in the '579 patent to indicate that providing compositions other than phospholipid compositions in a cosmetic carrier could be achieved. In the absence of such teachings, one of skill in the art would have no reasonable expectation of success in making cosmetic compositions comprising histamine, histamine dihydrochloride, histamine diphosphate, other histamine salts, esters, prodrugs, histamine-receptor agonists, serotonin, 5HT agonists, and endogenous histamine releasing compounds based on the disclosure of the '579 patent. Therefore, the cited art does not provide a reasonable expectation of success for practicing the claimed methods.

Accordingly, because there is no teaching or suggestion to make the cited combination of references and there is no reasonable expectation of success in practicing the claimed methods based on the disclosures of these references, a rejection based on a *prima facie* case of obviousness is improper. Thus, Applicant respectfully submits that the pending claims are not

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obvious under 35 U.S.C. § 103 in view of WO '968, WO '601 and the '579 patent, and requests that this rejection be withdrawn.

### CONCLUSION

For the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action have been addressed and that the application is in condition for allowance. Accordingly, Applicant requests the expeditious allowance of the pending claims.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call the undersigned to discuss such issues.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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